

### **REMARKS**

After entry of this amendment, claims 1-25 will be pending. Claims 1-24 stand rejected. Claims 1, 9, 17 and 22 are amended. Claim 25 is added. Support for the amendments and new claim can be found, *inter alia*, in paragraphs [0006], [0008], and [0036] of the specification as filed. No new matter is added herein.

Applicants have considered the Office action, including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

### **Rejections Under 35 U.S.C. § 102**

The Examiner rejects claims 1, 9, 17-18, 22, and 24 under 35 U.S.C. § 102(b) as anticipated by United States patent no. 6,277,108 to McBroom et al. ("McBroom"). To be anticipatory, a single prior art reference must explicitly or inherently teach each and every element of the claimed invention. MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Applicants respectfully submit that McBroom fails to meet this standard.

Claim 1 recites "a *tearable* radiopaque marker" that "may be split into two or more pieces ... *by tearing said sheath body*["] (Emphasis added.) Claim 9 recites "a *tearable* radiopaque marker" that "may be split into two or more pieces ... *by tearing said radiopaque marker*["] (Emphasis added.) Claim 17 recites that the "first marker portion may be split apart from a remainder of said radiopaque marker ... *by tearing said sheath body*["] (Emphasis added.) Claim 22 recites "a *tearable*, contiguous radiopaque ring" that "may be broken *by tearing*." (Emphasis added.) Thus, each of the independent claims recites that the radiopaque ring may be split or broken by tearing—that is, by pulling apart.

McBroom, on the other hand, teaches that the marker band is slittable—that is, able to be cut through the use of a slitter, such as that illustrated in FIG. 2 and described at McBroom, col. 4:15-22. *E.g.*, McBroom, col. 4:52-54 ("In one embodiment, the marker band 330 comprises a thin marker band which allows for the marker band to

be slittable."); col. 5:43-46 ("[T]he reduced mass of the braided material 620 allows for the amount of slitting force to be reduced, thereby facilitating the slittable nature of both the sheath and the marker band 600"). Applicants respectfully submit that McBroom does not teach that the maker band may be split by tearing (that is, pulling apart) as in the claimed invention.

Applicants therefore submit that McBroom fails to teach each and every element of, and therefore cannot anticipate, claims 1, 9, 17, and 22. Claims 18 and 24 depend, respectively, from claims 17 and 22, and are allowable for at least the same reasons. Applicants accordingly request reconsideration and withdrawal of the rejection under section 102.

#### **Rejection Under 35 U.S.C. § 103**

The Examiner rejects claims 2-8, 10-16, 19-21, and 23 under 35 U.S.C. § 103 as obvious over McBroom in view of United States patent no. 6,562,049 to Norlander et al. ("Norlander"). Applicants respectfully disagree.

Though the prior art references need not teach or suggest each and every limitation of a claim for that claim to be obvious, Applicants contend that the differences between the rejected claims and the references cited are sufficiently great so as to render the claimed invention non-obvious to one of ordinary skill in the art at the time the invention was made. Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57527-28 (Oct. 10, 2007) ("[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on *what such a person would have reasonably expected to have been able to do in view of that knowledge.*") (emphasis added). In particular, Applicants contend that the cited references do not teach or suggest a radiopaque ring that may be split apart or broken by tearing, and thus one of ordinary skill in the art would not have learned the claimed invention from the asserted references.

Claims 2-8 depend from claim 1, claims 10-16 depend from claim 9, claims 19-21 depend from claim 17, and claim 23 depends from claim 22. The shortcomings of McBroom with respect to claims 1, 9, 17, and 22 are discussed at length above. These shortcomings are not addressed by the addition of Norlander, which Applicants submit also does not teach or suggest a radiopaque ring that may be split apart or broken by tearing. Accordingly, Applicants submit that the claimed invention is substantially different from, and therefore not obvious over, the asserted combination of references. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

#### **Remarks on New Claim 25**

Claim 25 recites that "the contiguous radiopaque ring is bonded to the distal end of the sheath body and *the score line of the contiguous radiopaque ring is hollow.*" (Emphasis added.) That is, the score line is not filled with a polymer or binding agent. Specification, para. [0036].

McBroom, on the other hand, teaches that "the aperture 410 [of marker band 400] is sized such that the material of the sheath 300 is disposed in the aperture 410 during the thermoforming process." McBroom, col. 5:7-10. See also McBroom, col. 5:33-35 ("In addition, the perforations allow for a mechanical bond to occur between the marker band and the sheath tubing wall when the sheath is thermoformed.").

Applicants therefore submit that McBroom encourages filling the score line with polymer material as part of the bond between McBroom's marker band and McBroom's sheath, in stark contrast to the claimed invention. Norlander also does not teach or suggest that a radiopaque ring including a hollow score line. For at least these reasons, claim 25 is allowable.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

Applicants have provided for a two (2) month extension of time concurrently herewith. If any further extension of time is deemed necessary for this submission to be considered timely, Applicants hereby petition therefor.

Applicants believe that a fee of \$50 is due for the net addition of claims herein. Authorization is hereby granted to charge any fees, including fees for the net addition of claims and for any further extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-044600US/82410-0054.

Respectfully submitted,

**WILEY REIN LLP**

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